UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA; the States of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, and WISCONSIN; the DISTRICT OF COLUMBIA, the CITY OF CHICAGO, and the CITY OF NEW YORK *ex rel*., and OSWALD BILOTTA, Plaintiffs, -against- NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	**11 Civ. 0071 (PGG)**

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT NOVARTIS PHARMACEUTICALS CORPORATION'S MOTION TO EXCLUDE THE TESTIMONY OF GRAHAM T. MCMAHON

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Defendant Novartis Pharmaceuticals Corporation ("NPC") respectfully submits this motion to exclude the expert testimony of Dr. Graham T. McMahon.

PRELIMINARY STATEMENT

In an attempt to identify pharmaceutical promotional programs that purportedly "lack medical educational purpose", Dr. McMahon created three criteria or "markers". Based on Dr. McMahon's markers, the Government will argue to the jury that tens of thousands of doctors attended NPC promotional events at which they received no educational value and, therefore, that the events served as kickbacks and that NPC intended as such.

For the following reasons, Dr. McMahon's markers do not meet any of the requirements for admission of expert testimony and cannot withstand scrutiny under Federal Rules of Evidence 702 and 403 or Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993).

First, Dr. McMahon's opinions are unreliable because he relies on groundless and speculative assumptions, not on facts or data from the record of what actually occurred at specific events, and he applies no identifiable, let alone reliable, methodology to those assumptions to create and apply his markers. (Section I.)

Second, according to the Government itself, Dr. McMahon opines on common sense and NPC's intent—both of which fall squarely within the fact-finding job of the jury and are impermissible subjects for expert testimony. (Section II.)

Third, Dr. McMahon's conclusions, premised on his experiences in unrelated non-promotional medical education, are not relevant to the promotional programs at issue here. (Section III.)

BACKGROUND

Dr. McMahon is the President and Chief Executive Officer at the Accreditation Council for Continuing Medical Education ("ACCME") and represents that he is an expert in "[m]edical education" based on a "variety of experiences" concerning medical student education and accredited continuing medical education ("CME") programs.[1] The standards for the non-promotional, accredited CME programs that Dr. McMahon oversees "ensur[e] that physicians were presented only balanced information without commercial bias". (McMahon Rep. ¶ 32.) Dr. McMahon has also rejected "the premise that there's the potential for useful educational value from promotion and marketing events" and testified that his "personal contention is that it's not in the best interest of science or our society to have such promotion and marketing events manipulating physician's behavior". (McMahon Dep. Tr. at 144:15-24.) Although Dr. McMahon's experience is solely in connection with non-promotional medical education and although he expressed a personal bias against promotional programs, he nonetheless purports to opine on NPC's promotional programs. (Dr. McMahon has not attended a single speaker program since 2000, and has never attended a NPC program at any time. (Id. at 10:10-17.)) Specifically, the Government asked Dr. McMahon to "identify characteristics of activities that do not meet the standards for medical education in the United States and therefore lack medical educational purpose". (McMahon Rep. ¶ 11.) He was also asked "to determine whether certain types of activities that took place with respect to promotional events sponsored by Novartis

[1] (Declaration of Benjamin Gruenstein in Support of Novartis Pharmaceuticals Corporation's Motions To Exclude the Proffered Opinions of Plaintiffs' Experts ("Gruenstein Decl."), Exhibit ("Ex.") 7, Expert Report of Graham T. McMahon (hereinafter "McMahon Rep.") ¶¶ 5-8; Gruenstein Decl. Ex. 8, McMahon Deposition Transcript Excerpts (hereinafter "McMahon Dep. Tr.") at 8:12-21.)

Pharmaceutical Corporation ('Novartis') inherently lacked educational value or educational purpose". (Id.)

To accomplish his assignment, Dr. McMahon created three markers that he claims "identify an activity that inherently lacks educational purpose":

- "A physician attends three or more events related to the same drug within six months."
- "A physician is a speaker at a speaker program on a drug and then subsequently attends a speaker program on the same drug within six months."
- "A physician attends three or more events within twelve months where the per person food and beverage spend for each event equals or exceeds $125."

(Id. ¶ 54). According to the Government, these "criteria that Dr. McMahon uses to identify activity that inherently lacks educational purpose . . . are common-sense metrics that, with or without Dr. McMahon's testimony, a jury could conclude are evidence of kickbacks". Mem. of Law in Opp'n to Def.'s Mot. for Summ. J. and in Supp. of the U.S.A.'s Cross-Mot. for Partial Summ. J. at 28-29, ECF No. 230. Dr. McMahon concluded that when these markers were met, NPC's intent was not to educate; as the Government puts it, Dr. McMahon opined "that it would be so unlikely that clinicians would learn anything of value through excessive repeat attendance that these programs cannot have been constructed with an intent to educate". Id. at 8. Dr. McMahon then also identified several "other indicia of activities that lack educational value or purpose", including, for example, "inappropriate venue" and "inappropriate audience". (McMahon Rep. at Section V.)

In deriving his markers, Dr. McMahon relied on a number of assumed facts and circumstances regarding NPC's events, which, again, he has never attended. For example,

relying on the expert report of Dr. Stanley Schneller[2], Dr. McMahon assumed that the medical information discussed at each NPC event on a particular drug was "duplicative" and "similar". (Id. ¶¶ 56, 59.) He assumed "that the slide presentations at speaker programs were delivered in full". (Id. ¶ 54.) He presumed that "subsequent discussion would be necessarily limited by the basic constructs presented" and that "the attendance of diverse or new attendees at a repeat event, or the recruitment of a different speaker, would [not] shift an event to become more relevant, or to have introduced previously unrecognized complexity through case conversation". (Id. ¶¶ 69, 70.) And Dr. McMahon presumed that "[r]oundtables were constructed in a way that were led by a sales representative who in many cases has limited knowledge and difficulty to engaging in complex problem-solving". (McMahon Dep. Tr. at 119:4-7.) To set the $125 food-and-beverage-spend figure for his third marker, Dr. McMahon relied on Zagat surveys. (McMahon Rep. ¶ 76.)

Dr. McMahon made these assumptions and divined his markers without reviewing any depositions or NPC slide decks. (McMahon Dep. Tr. at 52:24-53:14; 61:2-9.) Therefore, Dr. McMahon knew neither "the topics that were covered in these speaker programs", nor whether "specific [patient] cases were discussed". (Id. at 59:23-60:3; 95:18-22.) And he did not perform any after-the-fact investigation to corroborate the validity of his markers: for example, he did not speak to any doctors who went to three or more NPC promotional programs within six months, or who had been speakers and then attendees at NPC speaker programs within six months. (Id. at 52:11-23.) Moreover, he relied on the Zagat surveys to come up with his

[2] NPC is also moving separately to exclude the expert testimony of Dr. Schneller.

third marker without knowing whether the Zagat surveys were based on scientific studies or how they determined the average cost per meal at high-end restaurants. (Id. at 138:11-20; 140:4-7.)

Dr. McMahon did not provide a methodology by which anyone else could reproduce his markers or "indicia", instead testifying, "I based construction of the criteria on my years of experience and my training." (Id. at 52:6-10.) Notably, despite basing his markers for NPC's promotional events on his experience with accredited CME programs, Dr. McMahon does not apply the markers to his non-litigation work in accrediting CME programs. (See, e.g., id. at 50:18-21; 127:14-128:13 (testifying that there are no CME rules preventing a speaker at an event from later attending the event for credit).) And Dr. McMahon did not point to any other organization that uses his markers to evaluate educational quality or purpose. In short, this is a made-for-litigation methodology, created by someone with no personal knowledge of what he purports to evaluate.

LEGAL STANDARD

"[T]he Rules of Evidence—especially Rule 702—[]assign[s] to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." Daubert, 509 U.S. at 597. "[A]ny step that renders [an expert's] analysis unreliable . . . renders the expert's testimony inadmissible". Amorgianos v. Nat'l R.R. Passenger Corp., 303 F.3d 256, 267 (2d Cir. 2002) (emphases in original). The party seeking to introduce and rely on expert testimony bears the burden of establishing by a preponderance of the evidence that the proposed expert and the testimony meet the requirements of Rule 702. United States v. Williams, 506 F.3d 151, 160 (2d Cir. 2007).

"[T]he district court should consider the indicia of reliability identified in Rule 702, namely (1) that the testimony is grounded on sufficient facts or data; (2) that the testimony

'is the product of reliable principles and methods'; and (3) that 'the witness has applied the principles and methods reliably to the facts of the case.'" Amorgianos, 303 F.3d at 265. Where an expert's theory rests, in part, on a significant assumption that "is unsupported by the record", that theory "is not based on sufficient data and is not the product of reliable principles and methods". Hunt v. CNH Am. LLC, 857 F. Supp. 2d 320, 343 (W.D.N.Y. 2012).

To analyze the reliability of an expert's principles and methods, the Supreme Court has identified four factors: (1) "whether the theory or technique in question can be (and has been) tested"; (2) "whether [the theory or technique] has been subjected to peer review and publication"; (3) the theory or technique's "known or potential error rate and the existence and maintenance of standards controlling [the theory or technique's] operation"; and (4) "whether [the theory or technique] has attracted widespread acceptance within a relevant scientific community". Daubert, 509 U.S. at 593-94. The Daubert factors do not constitute a "'definitive checklist or test'" and must be tailored to the facts of a particular case; however, "'some of Daubert's questions can help to evaluate the reliability even of experience-based testimony'". Donnelly v. Ford Motor Co., 80 F. Supp. 2d 45, 48 (E.D.N.Y. 1999) (quoting Kumho Tire Co. v. Carmichael, 526 U.S. 137, 150-51 (1991)).

Moreover, "nothing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the ipse dixit of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997). "Thus, when an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached, Daubert and Rule 702 mandate the exclusion of that unreliable opinion testimony." Amorgianos, 303 F.3d at 266.

To be admissible, an expert's testimony must also be relevant. An expert's opinion is relevant if "the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue". Fed. R. Evid. 702. To be helpful, expert opinion cannot invade the fact-finding province of the jury. See Nimely v. City of New York, 414 F.3d 381, 397 (2d Cir. 2005). The opinion must also be "sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute". Daubert, 509 U.S. at 591 (internal quotation mark omitted). "Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility." Id. at 591-92.

Even relevant expert testimony may be excluded under Federal Rule of Evidence 403: "Rule 403 permits the exclusion of relevant evidence 'if its probative value is substantially outweighed by the danger of unfair prejudice, confusion or the issues, or misleading the jury . . . .'" Daubert, 509 U.S. at 595 (quoting Fed. R. Evid. 403). "Expert evidence can be both powerful and quite misleading because of the difficulty in evaluating it. Because of this risk, the judge in weighing possible prejudice against probative forces under Rule 403 . . . exercises more control over experts than over lay witnesses." Id. (internal quotation marks omitted).

ARGUMENT

I. DR. MCMAHON'S OPINIONS ARE UNRELIABLE BECAUSE THEY ARE NOT SUPPORTED BY SUFFICIENT FACTS AND ARE NOT THE PRODUCT OF RELIABLE PRINCIPLES OR METHODS.

"An expert's opinions that are without factual basis and are based on speculation or conjecture should be excluded from consideration at summary judgment or trial." Sparta Commercial Servs., Inc. v. DZ Bank, 680 F. App'x 17, 19 (2d Cir. 2017). "At trial, proffered 'expert testimony should be excluded if it is speculative or conjectural[]'; the '[a]dmission of

expert testimony based on speculative assumptions is an abuse of discretion'". Major League Baseball Props., Inc. v. Salvino, Inc., 542 F.3d 290, 311 (2d Cir. 2008) (citations omitted) (quoting Boucher v. U.S. Suzuki Motor Corp., 73 F.3d 18, 21-22 (2d Cir. 1996)). "An expert's data and methodology [are] reliable if there is a 'rigorous analytical connection between [the] methodology and the expert's conclusions.'" Anderson News, L.L.C. v. Am. Media, Inc., No. 09 Civ. 2227(PAC), 2015 WL 5003528, at *1 (S.D.N.Y. Aug. 20, 2015) (quoting Nimely, 414 F.3d at 396). "Daubert's gatekeeping requirement" is meant "to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Kumho Tire Co., 526 U.S. at 152; see also Fed. R. Evid. 702 advisory committee's note to 2000 amendment ("The trial court's gatekeeping function requires more than simply 'taking the expert's word for it'. . . . The more subjective and controversial the expert's inquiry, the more likely the testimony should be excluded as unreliable." (citation omitted)).

Through his markers, Dr. McMahon purports to predict what happened at thousands of particular events and whether and to what extent thousands of doctors learned something of value. But Dr. McMahon is not capable of, and certainly not expert at, making such factual predictions. Nevertheless, he purports to do so by relying on speculative assumptions without any reliable methodology.

In crafting his first two markers—(i)"[a] physician attends three or more events related to the same drug within six months" and (ii) "[a] physician is a speaker at a speaker program on a drug and then subsequently attends a speaker program on the same drug within six months" (McMahon Rep. ¶ 54)—Dr. McMahon simply assumed that the medical information discussed at each of NPC's events was "duplicative" and "similar" (id. ¶¶ 56, 59) and "that the

slide presentations at speaker programs were delivered in full" (id. ¶ 54). He also assumed that "subsequent discussion would be necessarily limited by the basic constructs presented" and that "the attendance of diverse or new attendees at a repeat event, or the recruitment of a different speaker, would [not] shift an event to become more relevant, or to have introduced previously unrecognized complexity through case conversation". (Id. ¶¶ 69, 70; see also McMahon Dep. Tr. at 62:2-6 ("The likelihood of educational value—or, the likelihood that robust case conversations with deliberate feedback, practice occurring in a Q&A following a speaker program as outlined by Novartis is low.").) And Dr. McMahon presumed that "[r]oundtables were constructed in a way that were led by a sales representative who in many cases has limited knowledge and difficulty to engaging in complex problem-solving". (McMahon Dep. Tr. at 119:4-7.)

Although these assumptions are critical to his first two markers, Dr. McMahon had no factual basis for them. Dr. McMahon did not review a single deposition prior to preparing his report. (Id. at 52:24-:53:14.) He did not review any of the NPC slide deck presentations, (id. at 61:7-9); he merely relied on the report of another Government expert, Dr. Schneller, for a conclusion that the material in NPC's slide decks was simple, (id. at 61:2-9). Dr. McMahon did not "know one way or another whether[,] during [NPC's speaker program] events[,] specific [patient] cases were discussed". (Id. at 59:23-60:3.) Dr. McMahon did not even "know the topics that were covered in these speaker programs". (Id. at 95:18-22.) In addition, he has not attended a single speaker program during the relevant time period of this case, let alone an NPC speaker program. (Id. at 10:10-17.) Dr. McMahon also did nothing to corroborate or test his markers. For example, he did not "ask to see examples of doctors who went to three or more programs over six months, and then to corroborate that those doctors did

not actually get educational value from the program". (Id. at 52:11-17.) He did not "ask to identify any doctors who had been speakers and then attendees at programs and try to discern why they may have attended those events". (Id. at 52:18-23.)

Moreover, even if Dr. McMahon had reviewed depositions and been able to point to support for his assumptions within the testimony of the sales representatives who testified, he would have nowhere near the support necessary to render his assumptions applicable generally across the entire population of events. First, the Government cherry-picked the 18 sales representatives who testified, so they were necessarily a non-random sample of representatives. Second, those sales representatives who testified were unfamiliar with over 99% of all speaker programs and roundtables during the relevant time period; the sales representative deponents were uniformly only familiar with the events they personally hosted or attended.

Dr. McMahon similarly had an insufficient factual basis and no reliable methodology to justify his third marker that "[a] physician attends three or more events within twelve months where the per person food and beverage spend for each event equals or exceeds $125". (McMahon Rep. ¶ 54.) This marker purports to determine when a meal is so luxurious that the event at which it is served cannot be educational. (See id. ¶ 76 ("clearly identifies the activity as being about luxury entertainment").) Dr. McMahon did not describe or even profess to have any expertise in evaluating the luxuriousness of meals, the relative price of food, or the ways in which the cost of a meal impacts a program's educational value. Instead, he simply purports to use Zagat surveys to opine on the reasonableness of meal cost. (Id. ¶ 76.) Dr. McMahon admitted that he did not even understand the methodology behind how the surveys are conducted. He testified that he did not know whether the Zagat surveys on which he relied were based on scientific studies; he did not know how the Zagat surveys were prepared, including

whether they were based on actual restaurant prices or on surveys of people about their perception of price; and he did not know whether tax and tip were included in the Zagat data. (McMahon Dep. Tr. at 138:11-20; 140:4-7.) In addition, even if $125 for food and beverage cost could be a proxy for luxury, that would be irrelevant here because a restaurant's cost for its private room was often baked into NPC's cost data, which would inflate any average per-person spend.

Without any factual basis for his necessary assumptions, Dr. McMahon cannot be permitted to present to a jury the markers he has created. See Hunt, 857 F. Supp. 2d at 347 (expert opinions that are "speculative and not well supported" are inadmissible pursuant to Rule 702). In addition, any testimony concerning these unsubstantiated assumptions as the bases for Dr. McMahon's opinion would create a significant danger of unfair prejudice, confusion of the issues and misleading of the jury because the jury might believe the assumptions to be reliable, given that they were adopted by an expert witness. Id.

Furthermore, by couching his three markers in quantifiable terms, Dr. McMahon suggests precision where there is none. He provides no reliable methodology as to his first or second marker for how it is that attendance either at "three or more" events or after service as a speaker "within six months" inherently lacks educational purpose. (McMahon Rep. ¶ 54.) Instead, he simply claims to be "conservative" as to the number of events[3] and the time period[4].

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[3] (See McMahon Rep. ¶ 59 ("[W]hen setting a threshold for when a repeat event would be deemed to be inherently lacking in educational purpose or value, I decided to be conservative and take into account the unusual possibility that a clinician was unable to grasp the material on its first presentation"); id. ¶ 73 ("the speaker would have no educational gap to fill" because he or she "should be identified based on expertise with respect to the subject drug" and "attended training to become familiar with the subject drugs and the presentation material").)

And, without support, Dr. McMahon similarly asserts that for his third marker he came up with "three such events within the span of one year" "to be conservative". (Id. ¶ 78.)[5] These markers are classic ipse dixit of the expert.

"Subjecting [Dr. McMahon's markers] to Daubert scrutiny exposes immediately their unreliability, for nothing in his report explains the reasoning or methodology by which he reaches them." Donnelly, 80 F. Supp. 2d at 49; see also Scentsational Techs., LLC v. Pepsi, Inc., No. 13-cv-8645(KBF), 2018 WL 1889763, at *6 (S.D.N.Y. Apr. 18, 2018) (excluding expert opinion where expert "presents no methodology or analysis to support her assertion that Project Activo was 'more likely than not' to be successful"). Instead, Dr. McMahon testified: "I based construction of the criteria on my years of experience and my training." (McMahon Dep. Tr. at 52:6-10.) But Dr. McMahon does not explain how experience and training could provide any connection to his markers, let alone the "rigorous analytical connection" necessary to be reliable, Nimely, 414 F.3d at 396. "'[A] vague claim of "prior experience" cannot salvage an opinion . . . that is the product of guesswork. Otherwise, proffered expert witnesses could easily circumvent the requirements of Daubert by resorting to ambiguous claims of "past experience."'" LVL XIII

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[4] (See McMahon Rep. ¶ 60 ("I was equally conservative in setting the time period for which repeat attendance at an event would be deemed to be lacking in educational purpose or value" because "[t]he physician learning decay curve for practice-relevant material is long" and "authoritative national guidelines typically evolve no more frequently than once yearly"); id. ¶ 74 ("As with the prior criterion, I have settled on six moths as the applicable period to be conservative.").)

[5] Despite the fact that his third marker requires that a particular physician attends three or more events within twelve months, he uses an "average food and beverage spend" of $125, not the spend per the particular physician. (McMahon Rep. at Section IV(C) (emphasis added).) Even if Dr. McMahon had some basis for his $125 spend and two event caps, he does not explain how such a marker based on "average" spend makes any sense if the particular physician who attended more than twice had a food and beverage spend lower than the average for one or more of the events.

Brands, Inc. v. Louis Vuitton Malletier S.A., 209 F. Supp. 3d 612, 647 (S.D.N.Y. 2016) (quoting Hi Ltd. P'Ship v. Winghouse of Fla., Inc., No. 6:03-cv-116-Orl-22JGG, 2004 WL 5486964, at *4 (M.D. Fla. Oct. 5, 2004)) (precluding expert testimony because the expert "supplied virtually no insight into the considerations that shaped his qualitative analysis. There is thus no basis on which to hold that his opinions derive from a reliable methodology."), aff'd 720 Fed. App'x 24 (2d Cir. 2017).

"[T]here is simply too great an analytical gap between the data and the opinion proffered". Gen. Elec. Co., 522 U.S. at 146. Dr. McMahon's "criteria" should be "inadmissible, because [they] appear[] to be a label conjured up for litigation rather than the 'product of reliable principles and methods'". Anderson News, 2015 WL 5003528, at *3. In Anderson News, this Court ruled that an expert's so-called "super-plus factors", which would purportedly "'allow a strong inference of collusion'", were unreliable because (i) although the expert herself had previously published on them, "there [was] no scholarly or legal authority defining or using the term" and (ii) although the expert's prior publication "propose[d] an equation . . . to determine the 'strength' of a plus factor", there was "no explanation of why 'super-plus factors' demonstrate a stronger inference of collusion than traditional 'plus factors'". Id. Indeed, Dr. McMahon's markers are even more unreliable than the "super-plus factors" this Court excluded in Anderson News. See id. Unlike the expert in that case whose opinions were excluded, id., Dr. McMahon has not previously published on his criteria. And, unlike the expert in Anderson News (whose opinions again were excluded), see id., Dr. McMahon has provided no equation or reproducible, tested method by which to arrive at his criteria.

Moreover, Dr. McMahon does not point to any other source that applies these particular markers to evaluate the educational quality or purpose of an event. In fact, although he

claims to be relying on his experience in accrediting Continuing Medical Education ("CME") courses to divine his markers here, Dr. McMahon himself does not even apply those criteria to his regular outside-of-litigation work in accrediting CME programs. (See, e.g., McMahon Dep. Tr. at 50:18-21; 127:14-128:12 (there is no rule at CMEs preventing a speaker at an event from later attending the event for credit).)[6] "[T]he fact that the [markers] ha[ve] not been adopted or used by anyone other than [Dr. McMahon] indicates that [these criteria] ha[ve] not been generally accepted by the scientific community." Anderson News, 2015 WL 5003528, at *3.

Dr. McMahon himself implicitly recognized the unreliability of his method because he testified that he did not know what happened at individual events and that of course there could be exceptions to his markers. (See, e.g., McMahon Dep. Tr. at 43:4-6 ("As I've said several times now, an educational activity can have value for an individual learner in the exception.").) He provides no way of determining, let alone estimating, how many exceptions there were or could be. That leaves NPC and the jury no scientific way to determine whether Dr. McMahon's marker-based predictions are right and to what degree of certainty.

Further, Dr. McMahon, by his own admission, did not "employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field". Kumho Tire Co., 526 U.S. at 152. For example, he opined that if an NPC event were held in a casino that "is another indicia that the purpose of the activity is not education, but

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[6] Likewise, Dr. McMahon does not provide any methodology for arriving at his "other indicia of activities that lack educational value or purpose", (McMahon Rep. at Section V), and he does not even apply these "indicia" in his unrelated, not-made-for-litigation CME accreditation work. (See, e.g., McMahon Dep. Tr. at 164:8-172:24 (testifying that although "inappropriate venue", such as a casino, is one of his additional "indicia" for purposes of this case, a CME event that took place in Las Vegas and actually advertised casino entertainment could "comply with CME requirements").)

entertainment" because such a "venue[] [is] not conducive to learning" and "would . . . be expected to be highly distracting and to have set a tone that is focused on entertainment, even if some of the activity was held in a private room". (McMahon Rep. ¶¶ 92-94.) However, when asked about his own accreditation organization allowing a CME program at a casino in downtown Las Vegas that advertised, "live Las Vegas CME and vibrant nightlife, shows and fine dining", Dr. McMahon conceded, "I can't comment on the individual program that you're describing without investigating it more thoroughly." (McMahon Dep. Tr. at 168:2-169:13.) Nevertheless, Dr. McMahon purports to testify here regarding markers that he applies to thousands of NPC speaker and roundtable programs throughout the country over a ten-year period without any investigation of the events, let alone the "thorough[]" investigation he testified is necessary for CME accreditation of a single event outside of litigation.

II. DR. MCMAHON'S OPINIONS IMPERMISSIBLY INVADE THE JURY'S FACT-FINDING ROLE.

The Government itself implicitly admits that Dr. McMahon's opinions are not the product of a reliable methodology by asserting that Dr. McMahon's markers are simply a matter of common sense. However, the law is clear that such testimony invades the province of the jury's fact-finding and should be excluded. Similarly, the Government's concession that Dr. McMahon opines on NPC's intent requires that Dr. McMahon's opinions be excluded.

A. Expert Opinions That Are No More Than a Matter of Common Sense Should Be Excluded.

The Advisory Note to Rule 702 provides that in determining whether the expert's testimony "assist[s] the trier", the relevant standard is "whether the untrained layman would be qualified to determine intelligently and to the best possible degree the particular issue without enlightenment from those having a specialized understanding of the subject involved in the

dispute". Fed. R. Evid. 702 advisory committee's note to 1972 proposed rules (internal quotation marks omitted). As a result, expert testimony "is unnecessary and properly excludable where 'all the primary facts can be accurately and intelligibly described to the jury, and if they, as [persons] of common understanding, are as capable of comprehending the primary facts and of drawing correct conclusions from them as are witnesses possessed of special or peculiar training, experience or observations in respect of the subject under investigation.'" United States v. Castillo, 924 F.2d 1227, 1232 (2d Cir. 1991) (quoting Salem v. U.S. Lines Co., 370 U.S. 31, 35 (1962)). The Second Circuit has made clear that even where the expert opinion in question concerns "a proper subject for expert testimony under Fed. R. Evid. 702, we have carefully circumscribed the use of such testimony to occasions where the subject matter of the testimony is beyond the ken of the average juror". Id.

The Government's own description of Dr. McMahon's opinions requires their exclusion under Rule 702 and Second Circuit precedent. According to the Government, "[t]he criteria that Dr. McMahon uses to identify activity that inherently lacks educational purpose—i.e., attending the same or similar event three times within six months, attending an event within six months of being the paid speaker for the same or similar event, and attending at least three events within 12 months with a per-person meal spend of at least $125, McMahon Rep. ¶ 54—are common-sense metrics that, with or without Dr. McMahon's testimony, a jury could conclude are evidence of kickbacks." Mem. of Law in Opp'n to Def.'s Mot. for Summ. J. and in Supp. of the U.S.A.'s Cross-Mot. for Partial Summ. J. at 28-29, ECF No. 230 (emphasis added). Indeed, the Government reiterated, "Drs. McMahon and Schneller's expert testimony confirmed what this Court understood as a matter of common sense, that doctors would not be expected to derive educational value from repeatedly attending events regarding the same well-known drugs

in a condensed amount of time". Id. at 22-23 (emphasis added) (citing McMahon Rep. ¶¶ 15-16, 22-74).

The Government's assertion that Dr. McMahon's three criteria are "common-sense metrics that, with or without Dr. McMahon's testimony, a jury could conclude are evidence of kickbacks" is a straightforward concession that jurors, "as [persons] of common understanding, are as capable of comprehending the primary facts and of drawing correct conclusions from them as [is]" Dr. McMahon. Castillo, 924 F.2d at 1232.

Dr. McMahon's testimony should also be excluded under Rule 403. Since the Government has asserted that Dr. McMahon's markers are a matter of common sense, any probative value Dr. McMahon's testimony could provide would be substantially outweighed by the danger of unfair prejudice. Fed. R. Evid. 403. "Expert testimony on a subject that is well within the bounds of a jury's ordinary experience generally has little probative value. On the other hand, the risk of unfair prejudice is real." United States v. Montas, 41 F.3d 775, 784 (1st Cir. 1994). That is because "[b]y appearing to put the expert's stamp of approval on the government's theory, such testimony might unduly influence the jury's own assessment of the inference that is being urged." Id. In other words, according to the Second Circuit, "expert testimony that usurp[s] . . . the role of the jury in applying . . . law to the facts before it, by definition does not aid the jury in making a decision; rather it undertakes to tell the jury what result to reach, and thus attempts to substitute the expert's judgment for the jury's". Nimely, 414 F.3d at 397 (alteration in original) (citation omitted) (internal quotation marks omitted); see also, e.g., Somnis v. Country Mut. Ins. Co., 840 F. Supp. 2d 1166, 1173 (D. Minn. 2012) ("[T]he Court must be particularly careful to exclude such testimony if it might lead the jury to simply rely on the expert's opinion and 'surrender[][its] own common sense.'" (alterations in original)

(quoting Westcott v. Crinklaw, 68 F.3d 1073, 1076 (8th Cir. 1995))). Admission of Dr. McMahon's testimony would put an expert's imprimatur on what the Government has clearly asserted more than once is a matter of common sense for the jury and would be unfairly prejudicial.

B. Expert Opinions about NPC's Intent Must Be Excluded.

"Inferences about the intent or motive of parties or others lie outside the bounds of expert testimony." In re Rezulin Prods. Liab. Litig., 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004). That is because "[t]he question of intent is a classic jury question and not one for the experts". Id. (alteration in original) (internal quotation marks omitted). Expert testimony about intent is "improper . . . because it describes lay matters which a jury is capable of understanding and deciding without the expert's help". Id. at 546 (internal quotation marks omitted).

This Court should exclude Dr. McMahon's testimony because it centers around NPC's intent and purpose in designing its speaker and roundtable events and inviting physicians to participate. Indeed, the Government itself makes clear that Dr. McMahon opines on NPC's intent, writing that Dr. McMahon and Dr. Schneller "explain that it would be so unlikely that clinicians would learn anything of value through excessive repeat attendance that these programs cannot have been constructed with an intent to educate". Mem. of Law in Opp'n to Def.'s Mot. for Summ. J. and in Supp. of the U.S.A.'s Cross-Mot. for Partial Summ. J. at 8, ECF No. 230 (emphasis added) (citing McMahon Rep.). Throughout his report and deposition, Dr. McMahon opined on the purpose behind NPC's events. (E.g., McMahon Dep. Tr. at 29:20-24 ("Q. And when you say 'the purpose,' you mean the purpose of the person who or company that is putting together this activity? A. The educational planner has a purpose in constructing an activity in a

particular form. When that planner constructs an activity that has low educational utility, then their purpose is clarified by doing so.").) Indeed, this was the essence of his assignment:

> "[T]he plaintiff has asked that I identify characteristics of activities that do not meet the standards for medical education in the United States and therefore lack educational purpose. The plaintiff also asked me to determine whether certain types of activities that took place with respect to promotional events sponsored by Novartis Pharmaceutical Corporation ("Novartis") inherently lacked educational value or educational purpose. Finally, I was asked to identify other indicia suggesting that an activity lacked either educational value to the attendee or an educational purpose."

(McMahon Rep. ¶ 11 (emphases added).) Dr. McMahon reiterated at his deposition that he was retained to opine on the "purpose" of "[t]he educational planner . . . in constructing an activity in a particular form". (McMahon Dep. Tr. at 29:17-24.)[7]

III. DR. MCMAHON'S OPINIONS WILL NOT HELP THE JURY DETERMINE A FACT IN ISSUE.

"Daubert's second criterion of 'fit' is essentially a requirement of relevance: 'Rule 702's "helpfulness" standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.'" Amorgianos v. Nat'l R.R. Passenger Corp., 137 F. Supp. 2d 147, 163 (E.D.N.Y. 2001) (quoting Daubert, 509 U.S. at 591-92), aff'd, 303 F.3d 256 (2d Cir. 2002). "A proffered expert opinion may fail to meet the fit requirement if it relates to facts or data that have not been adequately established in the case." Id. (internal quotation marks omitted). Here, Dr. McMahon's testimony is irrelevant because it does not fit the facts of this case.

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[7] In addition, such testimony would be unfairly prejudicial because it would in essence direct the jury how to find on NPC's intent. (See supra Section II(A).)

First, for the reasons explained above, Dr. McMahon's assumptions that are essential to his resultant markers are based on speculation and conjecture and do not fit the facts of the case. (See supra Section I.) Therefore, as a matter of law, his "opinion, even if reliable, does not fit the facts of the case, is not helpful to the trier of fact, and, thus, is inadmissible." Amorgianos, 137 F. Supp. 2d at 163.

Second, his opinions are not helpful, and will likely be confusing, because Dr. McMahon is essentially comparing apples—medical student education and accredited CME programs—with oranges—pharmaceutical promotional programs. Dr. McMahon does not claim to have authored any publications concerning promotional pharmaceutical speaker programs or roundtable events. He does not claim to have worked at, or advised, a pharmaceutical company. He has not even attended a promotional speaker program since 2000 and, therefore, has not attended a single promotional speaker event during the entire relevant time period of this case, let alone an NPC speaker program. (McMahon Dep. Tr. at 10:10-17.) Instead, Dr. McMahon claims expertise in "[m]edical education". (Id. at 8:12-13.) He bases that expertise on his "variety of experiences and training in how people and, in particular, students and physicians, learn, how you drive behavioral change, develop attitudes, and relate information to professionals". (Id. at 8:14-21.) Each of his "experiences" concerned medical student education and accredited CME programs; none of them relates to unaccredited, pharmaceutical promotional programs. (See McMahon Rep. ¶¶ 5-8.) Therefore, by relying for his expertise entirely on his experience with medical student education and accredited CME programs, Dr. McMahon must be relying on such programs to draw conclusions about NPC's promotional programs. However, Dr. McMahon's "scientific, technical, or other specialized knowledge" on medical student education and accredited CME programs will not "help the trier of fact to

understand the evidence or to determine a fact in issue" concerning NPC's promotional programs. See Fed. R. Evid. 702.

According to Dr. McMahon's own report, the standards for accredited CME programs "prohibit[] any commercial influence, direct or indirect, over CME content" and "ensure that CME planning decisions are made free of the control of a commercial interest". (McMahon Rep. ¶ 40.) That is very different from the purpose of pharmaceutical promotional programs, which are, by design, commercial marketing programs.

Moreover, even if Dr. McMahon's opinions were somehow relevant, they should be excluded under Rule 403. Dr. McMahon's opinions, anchored in his experience in programs designed to be free of a commercial message, have a significant risk of "unfair prejudice, confusing the issues, [and] misleading the jury" and, therefore, should be excluded under Rule 403. Fed. R. Evid. 403. See, e.g., In re Rezulin, 309 F. Supp. 2d at 545 (ruling, under Rule 403, that "it would be likely unfairly to prejudice and confuse the trier by introducing the 'experts'' opinions and rhetoric concerning ethics as alternative and improper grounds for decision on bases other than the pertinent legal standards" in a case where the principal issues were pharmaceutical manufacturing, labeling and marketing, not ethics). In addition, if Dr. McMahon is permitted to offer his markers as an expert, NPC will have to raise the irrelevant issues of non-promotional medical education and CME standards (inapplicable to the programs at issue) that will likely confuse the jury even further and waste time. "Whatever probative value the topic of [CME standards] has for [education in non-promotional programs] is substantially outweighed by the corresponding waste of time, danger of confusion, and unfair prejudice to" NPC. See In re Fosamax Prods. Liab. Litig., 645 F. Supp. 2d 164, 198 (S.D.N.Y. 2009) (excluding, under

Rule 403, expert testimony concerning supposed similarity between medical condition caused by related but different drug from that at issue).

CONCLUSION

For the foregoing reasons, NPC respectfully requests that this Court preclude the testimony of Dr. McMahon.

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Respectfully submitted,

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